FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

VIA SIGNATURE CONFIRMED DELIVERY

October 9, 2020

Brandon K. Knott
Pharmacist-in-Charge and Owner
Poulsbo Compounding Pharmacy LLC, dba Cascade Specialty Pharmacy
325 NE Hostmark Street
Poulsbo, WA 98370-6668

Dear Mr. Knott:

From March 11, 2019, to April 17, 2019, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Poulsbo Compounding Pharmacy LLC dba Cascade Specialty Pharmacy, located at 325 NE Hostmark Street, Poulsbo, WA, 98370. During the inspection, the investigator observed deficiencies in your practices for producing drug products, which put patients at risk.

FDA issued a Form FDA 483 on April 17, 2019. FDA acknowledges receipt of your facility's responses, dated April 30, 2019, September 24, 2019, and October 30, 2019. Based on this inspection, it appears that you produced drugs that violate the Food, Drug & Cosmetic Act (FDCA).

A. Violations of the FDCA

Adulterated Drug Products

The FDA investigator noted that drug products were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, the investigator observed:

1. Your firm failed to ensure certification of the ISO 5 area before it was utilized in drug production. In addition, your firm failed to perform adequate smoke studies under dynamic conditions to demonstrate unidirectional airflow within the ISO 5 area. Therefore, your products intended to be sterile are produced in an environment that may not provide adequate protection against the risk of contamination.

Division of Pharmaceutical Quality Operations IV
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2. Your media fills were not performed under the most challenging or stressful conditions. Therefore, there is a lack of assurance that your firm can aseptically produce drug products within your facility.

3. You have a (b) (4) (b) (4), which may allow for the influx of lesser quality air into a higher quality air area.

4. Your firm used non-sterile cleaning pads to disinfect the inside of the ISO 5 area. In addition, our investigator observed fraying of gauze pads during preparation, cleaning, and disinfection prior to sterile drug production.

5. Production areas and equipment were visibly dirty. Specifically,
   a. Mortar and pestles used in the production of non-sterile drug products were observed to have stains.
   b. Dust was observed on the top surface of a (b) (4) hood.
   c. Visible residue, debris, powders, and crystalline material was observed on the lab bench space between the (b) (4) hoods and the wall.
   d. Residue was observed on the lab bench under balances and other equipment.

6. Your firm produced hazardous drug products without providing adequate containment, segregation, or cleaning of work surfaces and utensils, and personnel to prevent cross-contamination.

7. Your firm failed to confirm that the quality of (b) (4) was suitable for its intended use in the production of non-sterile drug products.

Under section 301(a) of the FDCA [21 U.S.C. § 331(a)], the introduction or delivery for introduction into interstate commerce of any drug that is adulterated is a prohibited act. Further, it is a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated.

B. Corrective Actions

We have reviewed your firm's responses to the Form FDA 483, dated April 30, 2019, as well as your subsequent responses. Regarding your responses related to the insanitary conditions, some of your corrective actions appear to be adequate. However, we cannot fully evaluate the adequacy of the following corrective actions described in your response because you did not include sufficient information or supporting documentation:

1. In response to Observation 1 of the Form FDA 483, regarding certification of the ISO 5 area before it was utilized in drug production, you have stated that the issue was caused by a miscommunication and have updated your

communication procedure with your contract testing company and implemented an alert system to notify your management when expected results should be anticipated. Please provide your most recent certification reports for the Biological Safety Cabinet (BSC) and your cleanroom.

2. You committed to (b) (4) by October 31, 2019, to eliminate the (b) (4). However, you have not provided evidence to demonstrate this corrective action has been completed. Furthermore, you committed to provide a facility plan regarding (b) (4) by December 1, 2019. However, we have not received any updates. Please provide an update on this plan and if you intend to (b) (4).

Regarding your responses related to the insanitary conditions, the following corrective action appears deficient. Specifically, in response to Observation 2A of the Form FDA 483, you stated you conducted smoke studies on May 11, 2019 and provided the videos. We have reviewed the smoke studies and are unable to visualize laminar air flow as the smoke appeared heavy and dense with several ebbs noted. In addition, it appears that the smoke studies were not performed under dynamic conditions as personnel inside the cleanroom did not simulate aseptic manipulations inside the ISO 5 area, including the use of components and equipment, such as a repeater pump.

C. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

Within thirty (30) working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct the violations. Please include an explanation of each step being taken to prevent the recurrence of the violations, as well as copies of related documentation. If you do not believe that the products discussed above are in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within thirty (30) working days, state the reason for the delay and the time within which you will complete the correction.

Send your electronic reply to ORAPHARM4_RESPONSES@fda.hhs.gov or mail your reply to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
U.S. Food & Drug Administration
19701 Fairchild Road

Irvine, California 92612-2506

Please identify your response with unique identifier **608237**.

If you have questions regarding the contents of this letter, please contact Maria P. Kelly-Doggett, Compliance Officer via email to maria.kelly-doggett@fda.hhs.gov or by phone at (425)-302-0427 and reference unique identifier **608237**.

Sincerely,

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

SP: mk